UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AZUR PHARMA, INC.,	:	
	:	**No. 10 Civ. 207 (NRB)**
Plaintiff,	:	
v.	:	
	:	
TRIGEN LABORATORIES, INC.,	:	
	:	
Defendant.	:	

PLAINTIFF'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

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TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Page(s)

Cases

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AZUR PHARMA, INC.,	
Plaintiff,	10 Civ. 207 (NRB)
v.	
TRIGEN LABORATORIES, INC.,	
Defendant.	

Plaintiff Azur[1] respectfully submits this reply memorandum of law in further support of its motion for a preliminary injunction.

PRELIMINARY STATEMENT

The parties agree that:

1. Trigen markets its prescription prenatal Taron and Folivane multivitamin/mineral tablets and capsules as lower-cost alternatives, or substitutes, for the Gesticare® Products.[2]

2. Drug data publishing services identify alternative or substitutes to brand product prescription prenatal vitamins.[3]

3. Drug data publishing services, physicians, pharmacists and other participants in the marketplace for prescription drugs rely upon drug manufacturers to accurately describe their products.[4]

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[1] Capitalized terms used in this reply memorandum of law have the same meaning as set forth in Azur's initial memorandum of law in support of its motion for a preliminary injunction.
[2] Trigen's Memoranda [*sic*] Of Law In Opposition to Azur's Motion for Preliminary Injunction ("Trigen Opp. Brief") at 1-2.
[3] Id.
[4] Trigen Answer ¶¶ 32 and 34.

4. Trigen informed the drug data publishing services, and placed on its Product inserts, that the Trigen Products have "been designed to avoid interference of calcium and iron absorption through a pH-dependent *biphasic release* of these minerals at different sites in the gastrointestinal tract. The immediate-release iron dissolves at gastric pH, while the *delayed-release* enteric coated *calcium granules dissolve in the small intestine* ..." (emphasis added). Trigen also informed the drug data publishing services and included on the package label and inserts the purported ingredients and ingredient strengths of the Products.[5]

5. At least one such service (First Databank) has linked the Trigen Products with the Gesticare® Products.[6]

6. As a result, pharmacists may fill, and have filled, prescriptions for Gesticare® Products with Trigen Products, and Azur has lost a portion of its market.[7]

Azur's moving papers as further supplemented herein, demonstrate that Trigen has provided false information to the drug data publishing services, and misrepresented its ingredient strengths on the labels and in the inserts. Trigen concedes that Azur has suffered, and will continue to suffer as a result of Trigen's false advertising. Trigen therefore is in violation of the Lanham Act, and a preliminary injunction should issue.

Even a cursory examination of the response papers reveals that Trigen does not, and cannot, rebut Azur's proof that the Trigen Products are not biphasic, or that some of the ingredients or their strengths do not conform to the information advertised and promoted by Trigen. Instead, they submit declarations replete with inappropriate ad hominem attacks on the independent scientists that performed the testing on the Trigen Products in an attempt both to confuse the issues before this Court and, ultimately unsuccessfully, to challenge the testing methodology utilized by the independent laboratories. As shown below and in the accompanying declarations submitted by Feridoon Bakhshi ("Bakhshi Supp. Dec.") and Cormac Long ("Long Dec."), the challenges are without merit. Moreover, as will be shown, the predicate

[5] Hudy Declaration ("Hudy Dec.") ¶¶ 9-11, 14 and Exhibits A-D.
[6] Id.
[7] Id.

for the challenges relies on non-independent and scientifically invalid tests and, at times, on no testing at all.

In short, Trigen relies on slipshod and unacceptable testing procedures performed by its manufacturer to refute the results obtained by independent laboratory testing. Given that the Trigen Products (a) are not biphasic, (b) do not contain the ingredient strengths as advertised, (c) are not substitutes for the Gesticare® Products, and (d) their advertising and promotions run afoul of the Lanham Act, injunctive relief is appropriate.

STATEMENT OF FACTS

This memorandum of law relies on the statements set forth in the previous declarations submitted in support of this motion, as well as the Bakhshi Supp. Dec., Long Dec. and Declaration of Leo L. Esses, dated April 14, 2010 ("Esses Decl."), submitted herewith, which are incorporated by reference.

ARGUMENT

AZUR MEETS THE PRELIMINARY INJUNCTION STANDARD

Trigen argues that because Azur is allegedly seeking to alter the status quo, and seeks to obtain the ultimate relief it will get at trial, Azur must meet the higher burden of demonstrating that it will "more likely succeed than fail." Trigen Opp. Brief at 6. Although the difference between mandatory and prohibitory injunction is frequently unclear, *see, e.g., Tom Doherty Associates, Inc. v. Saban Entertainment, Inc.*, 60 F.3d 27, 34-5 (2d Cir. 1995), the distinction is not relevant here, given that Azur has met even the heightened standard.

We note, first, that Trigen's argument for a heightened standard because the preliminary injunction, if granted, would provide "Azur with all of the relief sought which cannot be undone after trial," Trigen Opp. Brief at 7-8, is without merit. The heightened standard can only be justified

> when the issuance of an injunction will render a trial on the merits largely or partly meaningless, either because of temporal concerns, say, a case involving the live televising of an event scheduled for the day on which preliminary relief is granted, or because of the nature of the subject of the litigation, say, a case involving the disclosure of confidential information.

Tom Doherty, 60 F.3d at 35. In this case, all Trigen need do is cease its false and misleading advertising by correcting its labels and inserts, inform the drug data publishing services that the information it previously provided regarding the Trigen Products was false and it can then immediately return to the market. Clearly, the relief sought, if granted, can be undone.

In any event, Azur has demonstrated that it will more likely succeed than fail. Azur has demonstrated through independent testing consistent with scientific and industry standards that the Trigen Products are not substitutable for the Gesticare® Products because (i) the Trigen Products are not biphasic (Bakhshi Reply Dec. ¶ 8); and (ii) the Trigen Products falsely state the quantity/level of the Vitamin B12 and iodine in the Taron tablets, the iodine in the Folivane tablets, and the DHA and, by complete omission, the EPA in the DHA capsules for Taron and Folivane (Bakhshi Dec. Exs. F, G, H, and J; Bakhshi Supp. Dec. ¶ 22; Reuther Dec. ¶¶ 11, 15, and 20). Thus, the Trigen Products differ dramatically from the Gesticare® Products, and the injunctive relief requested should be granted in its entirety.

As set forth above, Trigen, in its opposition brief and through the Barkley Declaration, does no more than take pot shots at the testing procedures used, and results obtained, by Azur's independent experts. Although we refer this Court to the Supplemental Bakhshi Declaration submitted herewith for a comprehensive response to the misleading statement set forth in the Barkley Dec. and Declaration of David Ko ("Ko Dec."), we note for this Court's convenience the most salient points.

Azur (i) used independent laboratories (Bakhshi Supp. Dec. ¶ 17) (ii) to test Trigen's *finished products* (Bakhshi Supp. Dec. ¶¶ 11 and 25), (iii) subjecting them to both the stringent tests the Gesticare® Products underwent as well as to the most lenient standards permissible by the USP (Bakhshi Dec. ¶¶ 18-19), (iv) using a validated method in accordance with USP Edition 32: Oil and Water Soluble Vitamins with Minerals (Bakhshi Testimony at Exhibit A to Esses Decl. at 99:20-22and 100:14-17; Bakhshi Supp. Dec. at 21).

Trigen, in contrast, did not conduct any independent laboratory testing on its products whatsoever. Further, for the following reasons, its manufacturer's testing is fundamentally flawed. First, it did not conduct a test of the finished product DHA capsules at all (Ko. Dec. ¶ 21; Barkley Dec. ¶ 58), rendering the tests useless (Bakhshi Supp. Dec. ¶ 25). Except for only 2 (in one Folivane lot) or 3 (in a Taron lot) of the 14 ingredients, Trigen did not test the finished multivitamin/mineral tablet; in a second Taron lot, Trigen's manufacturer did not test any ingredients of the finished tablet whatsoever (Ko Dec. Exs. A-C; Bakhshi Supp. Dec. ¶ 25). Astonishingly, Trigen's manufacturer used testing methods validated only for other products, but *not for the Trigen Products at issue* (Ko. Dec ¶ 28), rendering all of its tests unreliable. (Bakhshi Supp. Dec ¶ 24).

Trigen's testing for biphasic release is scientifically invalid and of no value. Trigen tested the coated calcium granules separately, before they were processed into the tablet (Ko Dec. ¶ 20), a test that yields no information as to whether the coating strength is affected by the manufacturing process or the presence of other ingredients. (See Bakhshi Supp. Dec at 11). In effect, Trigen rigged the test. (Id.)

Realizing its tests are meaningless and that Laboval's tests are unassailable, Trigen resorts to distortions and a "so what" defense. Trigen essentially tells this Court, "so what" if the

ingredients are not what we tell the drug data publishing services, pharmacists, and physicians; "so what" if the product doesn't do what we say it does; "so what" if we advertise and promote our product as biphasic when it really is not. (Trigen Opp. Brief 19-25). Trigen essentially says that falsely characterizing its Products as biphasic is immaterial, because, in its view, the term "biphasic" is meaningless. (Barkley Dec. ¶¶ 30, 46). But the term is not meaningless. It means what Trigen itself states on its package insert: that the iron is fully absorbed before the calcium is released in the small intestine "to avoid interference of calcium and iron absorption." (Hudy Dec. Ex. B). The idea that "protracted" release of calcium in the stomach can be considered biphasic is simply not supported by any competent scientific study and contradicts Trigen's package inserts.

All the false statements are material. Trigen concedes that drug data publishing services used the information Trigen provided regarding drug delivery, ingredients and strengths, to link the Trigen Products to the Gesticare® Products. (Hudy Dec. ¶ 14). If the information Trigen supplied to these services accurately stated that their products do not have a biphasic release system, and that they do not have the same ingredients or ingredient strengths, the drug data publishing services would not have "linked" the Trigen Products with the Gesticare® Products and pharmacists would not fill Gesticare® prescriptions with Trigen Products.

Trigen has not refuted the evidence presented by Azur that Trigen's advertising and promotion is misleading and in violation of the Lanham Act. Accordingly, Azur has met the higher standard, and injunctive relief should issue.

ABSENT THE INJUNCTION AZUR WILL SUFFER IRREPARABLE HARM

The Gesticare® Products are unique and enjoy a distinct reputation as the only biphasic prenatal multivitamin/mineral on the market. The deficiencies of the Trigen Products

demonstrate the difficulties inherent in replicating the technology Azur developed for the Gesticare® Products. Trigen's entry into the market has eroded, and continues to erode, the distinct reputation that Azur, in general, and the Gesticare® Products, in particular, have. Moreover, prolonged exposure of the market to Trigen Products (which are not biphasic although claimed to be and are linked to the Gesticare® Products) will undermine the market's confidence in biphasic prenatal multivitamin/mineral products. This damage is irreparable. (Kelly Dec. ¶¶ 38-39; 45-48).

In the context of a Lanham Act case, an injunction should issue when the plaintiff demonstrates that advertisement for the offending product is literally false or that the advertisement, though literally true, is likely to mislead and confuse consumers. *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Company*, 938 F.2d 1544, 1548-49 (2d Cir. 1991). Indeed, where, as here, one company asserts a false comparison, "such false comparison ads give rise to a presumption of irreparable injury." *Johnson & Johnson-Merck Consumer Pharmaceuticals v. The Procter and Gamble Company*, 285 F. Supp. 2d 389 (S.D.N.Y. 2003); *McNeil-P.C.C., Inc.*, 938 F.2d at 1548-49; citing *McNeilab, Inc. v. American Home Products Corp.*, 848 F.2d 34, 38 (2d Cir. 1988) ("A misleading comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer").

Here, Trigen's advertisement and promotion of its products is literally false. First, Trigen advertises the Trigen Products as biphasic. They are not. Second, the ingredients in the Trigen Products are mislabeled and misrepresented. Trigen concedes that it provided this false information to the drug data publishing services for them to link on their databases the Trigen Products to the Gesticare® Products.

As Azur has conclusively demonstrated irreparable harm, Trigen's arguments concerning the sufficiency of monetary damages misses the mark. *See, e.g., Petereit v. S.B. Thomas, Inc.*, 63 F.3d 1169, 1186 (2d Cir. 1995) ("Major disruption of a business can be as harmful as its termination and thereby constitutes irreparable injury"); *Ticor Title Ins. Co. v. Cohen*, 173 F.3d 63, 68 (2d Cir. 1999)(loss of customer relationships constitutes irreparable harm); *Ahava v. J.W.G. Ltd.*, 250 F.Supp.2d 366, 371 (S.D.N.Y. 2003)("damage to reputation is difficult to prove or quantify"). Azur has expended significant sums to establish the reputation of the Gesticare® Products among the physicians and pharmacists. (Kelly Dec. ¶¶ 38-39). Trigen's false statements will, of necessity, erode the reputation of the Gesticare® Products in their eyes. *See McNeilab,* 848 F.2d at 38.

AZUR DID NOT DELAY BRINGING THIS MOTION

Trigen argues that Azur's "delay" in bringing this motion precludes a finding of irreparable harm. (Trigen Opp. Brief. at 8 – 9). This argument is pure "chutzpa."[8] As this Court is aware, Azur did not have access to the Trigen Products until they were launched. Although it was aware that Trigen was planning to launch a product that it would claim was substitutable, and was suspicious of such claim (prompting the various letters), Azur could not move for injunctive relief until it had samples that it could test. Indeed, Azur asked Trigen for samples, but Trigen claimed it had none available. Azur moved for injunctive relief immediately after the testing was completed. There can be no delay where Azur made good faith efforts to investigate Trigen's Products before initiating this motion. *King v. Innovative Books*, 976 F.2d 824, 831 (2d Cir. 1992)(author's eight month delay in filing claim did not rebut presumption of irreparable harm because he spent that time trying to obtain a copy of the infringing screenplay and movie).

[8] *Yates v. City of New York*, 2006 WL 2239403 at 1 (S.D.N.Y. Aug. 4, 2006).

TRIGEN'S FALSE STATEMENTS ARE ADVERTISING

Trigen contends that Azur fails to identify where Trigen has made false statements as part of commercial advertisement or promotion. (Trigen Opp. Brief. at 18–22). Trigen argues that its advertising package inserts are not considered commercial advertising because the patient sees it only after it purchases the product. (Trigen Opp. Brief at 20).[9] Trigen misses the point. Trigen's consumer is not the patient. Its consumers are the pharmacists and companies that supply pharmacists who rely on the drug data publishing services. (Hudy Dec. ¶ 9). As Trigen readily admits, it advertises and promotes the Trigen Products by supplying the inserts and information regarding its products to the drug data publishing services, "prior to offering its products" for the express purpose of having the Trigen Products linked with the Gesticare® Products. (Hudy Dec. ¶¶ 9 and 14 (salespeople "typically state that the Trigen Products are linked to the Gesticare® Products.")).

It is clear that Trigen too narrowly interprets "advertising or promotion." *PPX Enterprises, Inc. v. Audiofidelity, Inc.*, 746 F.2d 120, 124 (2d Cir. 1984) (because Section 43(a) is remedial and because its words are so clearly expansive, it should be broadly construed). Commercial advertising or promotion occurs in the context of (1) commercial speech; (2) made by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services; and (4) disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within that industry. *Gordon & Breach Sci. Publishers S.A. v. Am. Inst. of Physics*, 905 F. Supp. 169 (S.D.N.Y. 1995) (holding that any promotional statement directed at actual or potential purchasers falls within

[9] Trigen cites to *Gillette Co. v. Norelco Consumer Products Company*, 946. F. Supp. 115 (D. Mass. 1996) to support its argument that package inserts are not advertising and promotion. However, *Gillette* is inapposite. That case held that statements contained in product packaging "available to consumers only after purchase" are not advertising and promotion. *Id.* at 135. Here, Trigen supplied the relevant information to the drug data publishing services, pharmacists and physicians, in order to "affect their choice of purchase." *Id.* at 134; Hudy Dec. ¶¶ 9 and 14.

reach of the Lanham Act); *Fashion Boutique of Short Hills, Inc. v. Fendi USA*, 314 F.3d 48, 57 (2d Cir. 2002) (touchstone of commercial advertising is whether the party intends to penetrate the market and whether the contested representations are part of an organized campaign to penetrate the relevant market).

Trigen's campaign clearly meets this standard for advertising and promotion. First, Trigen's (false) claims that its products are biphasic and of the same ingredient strengths as depicted on the labels clearly is commercial speech. Second, Trigen is in direct competition with Azur. Third, the purpose of Trigen's (false) statements is for the direct and express purpose of influencing pharmacists and companies supplying pharmacists to buy its prenatal vitamins instead of Azur's products. Fourth, Trigen is disseminating the false and misleading information to the relevant market. Accordingly, Trigen's false statements are advertisements and promotions within the meaning, and run afoul of, the Lanham Act.

CONCLUSION

For all of the reasons set forth above and in Azur's initial moving papers, Azur respectfully requests this Court grant its motion for preliminary injunction and provide such other and further relief as this Court deems just and proper.

Dated: New York, New York
April 14, 2010

Respectfully submitted,
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